Section III 510(k) Summary

FEB 1 2013

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K123578

1. Date of Submission: Nov 8, 2012

2. Sponsor

Weigao Orthopaedic Device Co., Ltd.
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Anterior Cervical Plate System
Classification: II
Product Code: KWQ
Regulation Number: 888.3060

Review Panel: Orthopedic
Intended Use Statement:

The Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metatstatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

5. Predicate Device Identification

510(k) Number: K103491
Product Name: SKYLINE® Anterior Cervical Plate System
Manufacturer: Depuy Spine, Inc.

6. Device Description

The Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metatstatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

The plates with lowest profile are available several configurations, including different levels and lengths. It accommodates both semi-constrained constructs in which the variable screws are used for fixation, and constrained applications in which the fixed screws are rigidly locked to the plate. The plate attach to the anterior cervical spine with a minimum of four screws per plate.

The screws are also available in several configurations, including types (screw and self-tapping screw), locking methods (fixed locking and variable locking), diameters and various lengths.

All implants of Anterior Cervical Plate System are manufactured from Titanium alloy that meets the requirements of ASTM F136-11, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). The materials are

wildly used in the industry with well-known biocompatibility. No new materials are used in the development of this implant.

This system is provided non-sterile.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F1717-04, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, including the following items:

- Static compression bending test
- Dynamic compression bending test
- Static torsion test

8. Summary of Substantially Equivalent Comparison

The technological characteristics of proposed device and predicate device are the same.

Difference in dimension and test results of mechanical specifications between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Anterior Cervical Plate System, is determined to be Substantially Equivalent (SE) to the predicate device, SKYLINE® Anterior Cervical Plate System (K103491), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Weigao Orthopaedic Device Co., Ltd
% MID-LINK Consulting Co., Ltd
Ms. Diana Hong
General Manager
P.O Box 237-023
Shanghai, 200237
China

Letter dated: February 1, 2013

Re: K123578
Trade/Device Name: Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 16, 2012
Received: November 20, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director,
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K123578
Device Name: Anterior Cervical Plate System

Indications for Use:

The Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metatstatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S
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(Division Sign-Off)
Division of Orthopedic Devices
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